UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

July 31, 2007

MEMORANDUM

Subject: Efficacy Review for Sterilex Ultra Disinfectant Cleaner Solution 1, EPA Reg. No. 63761-8; DP Barcode: D339905

From: Ibrahim Laniyan, Microbiologist
Product Science Branch
Antimicrobials Division (7510P)

Thru: Tajah Blackburn, Acting Team Leader
Product Science Branch
Antimicrobials Division (7510P)

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Marshall Swindell PM 33/ Karen Leavy
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Sterilex Corporation
11409 Cronhill Drive, Suite L
Owings Mills, MD 21117

Formulation from the Label:

Active Ingredient(s)	% by wt.
n-Akyl (68% C_{12}, 32% C_{14}) dimethylethylbenzyl ammonium Chloride	3.00 %
n-Akyl (60% C_{14}, 30% C_{16}, 5% C_{12}, 5% C_{18}) dimethylbenzyl ammonium Chloride	3.00 %
Hydrogen peroxide	6.30 %
Other Ingredients	87.70 %
Total	100.00 %

I. BACKGROUND

The product, Sterilex Ultra Disinfectant Cleaner Solution 1 (EPA Reg. No. 63761-8), is an EPA-registered component of a two-part product. The product must be used with Sterilex Ultra Activator Solution. The mixture is approved cleaner and disinfectant with bactericidal and virucidal activities, for use on hard, non-porous surfaces in institutional, household, commercial, and hospital or medical environments. The applicant requested an amendment to the registration of this product to add disinfectant claims for effectiveness against *Staphylococcus aureus* – Methicillin Resistant, *Aspergillus niger*; and add/revise various marketing claims. Study was conducted at Nova Biologicals, Inc., located at 1775 East Loop 336, Suite 4, Conroe, TX 77301.

This data package contained a letter from the applicant's representative to EPA (dated March 17, 2007), EPA Form 8570-1 (Application for Pesticide), one study (MRID Nos. 471145-01), Statements of No Data Confidentiality Claims for the study, four reference labels, the last accepted label and the proposed label.

II. USE DIRECTIONS

The product is designed for use in disinfecting hard, non-porous surfaces such as floors, walls, countertops, stovetops, sinks, appliances, plastic cutting boards, chopping blocks, coolers, food processing equipment, kennel runs, cages, waterers, feeders, dressing plants, loading equipment, cabinets, highchairs, garbage cans, display equipment, tables, picnic tables, outdoor furniture, chairs, desks, telephones, doorknobs, shower stalls, bathtubs, sinks, urinals. The label indicates that the product may be used on surfaces composed of metal, stainless steel, glazed porcelain, glazed ceramic, sealed stone, hard fiberglass, plastic (polystyrene, polypropylene), enameled surfaces, finished/sealed and painted woodwork, finished floors, Formica, and vinyl upholstery. Directions on the proposed label provided the following information regarding preparation and use of the product as a disinfectant: Sterilex Ultra disinfectant Cleaner Solution 1, when mixed with Sterilex Ultra Activator Solution, is a one-step hospital disinfectant at 12.8 fl. oz. (each solution 1 & solution 2) per gallon of water (1:1:10).

For fungistat/mildewstat: Sterilex Ultra disinfectant Cleaner Solution 1, when mixed with Sterilex Ultra Activator Solution, control growth of mold and mildew organisms in a one-step at 12.8 fl. oz. (each solution 1 & solution 2) per gallon of water (1:1:10).

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments (Additional Organism): Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific microorganism on all carriers is required. In addition, plate count data must be submitted for each microorganism to demonstrate that a concentration of at least 10^4

microorganisms survived the carrier-drying step. These Agency standards are presented in DIS/TSS-1.

Supplemental Recommendations: An antimicrobial agent identified as a "one-step" cleaner-disinfectant, cleaner-sanitizer, or one intended to be effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5% blood serum. The organic soil level suggested is considered appropriate for simulating lightly or moderately soiled surface conditions. When the surface to be treated has heavy soil deposits, a cleaning step must be recommended prior to application of the antimicrobial agent. The effectiveness of antimicrobial agents must be demonstrated in the presence of a specific organic soil at an appropriate concentration level when specifically claimed and/or indicated by the pattern of use. The hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish disinfectant efficacy in hard water, all microorganisms (i.e., bacteria, fungi, viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same hard water tolerance level. All products tested by the recommended methods may be tested at the exposure periods prescribed in those methods. When an antimicrobial agent is intended to be effective in treating a non-porous surface, the Recommended Methods simulate this condition by using non-porous surface carrier (stainless steel cylinder or glass slide) specified in the method. The exposure period or manner of use necessary to provide efficacy must be featured prominently on the product label. These Agency standards are presented in DIS/TSS-2.

IV. BRIEF DESCRIPTION OF THE DATA

1. MRID 471145-01 "Disinfectant Efficacy Testing for Sterilex Ultra Disinfectant Cleaner Solution 1/Sterilex Ultra Activator Solution 2", by Paul J. Pearce; Project number: M19238 and M19239. Study conducted at Nova Biologicals Inc. Study completed on September 26, 2006.

This study was conducted against *Staphylococcus aureus* - Methicillin Resistant (ATCC 33591) (MRSA) and *Aspergillus niger* (ATCC 16404). Two lots sets (ST3-44-1/ST3-44-3 and ST3-44-2/ST3-44-4) of the product mix, Sterilex Ultra Disinfectant Cleaner Solution 1/Sterilex Ultra Activator Solution 2, were tested, according to AOAC Use-Dilution Methods for bacteria and fungi, against each of the target microorganisms for a contact time of 10 minutes at 20±1°C. The product was prepared by mixing 1.0 ml of Solution 1 and 1.0 ml of Solution 2 in 10 ml of 400 ppm AOAC Synthetic Hard Water. Five percent organic soil was added to the inocula; Tryptic Soy Broth was used as neutralizing subculture medium. Stainless steel penicylinders (carriers) were contaminated and dried at 32.5±2.5°C for 40 minutes. Ten carriers were tested for each of the batches set against each microorganism. Following exposure, the carriers were transferred to a primary neutralizing medium for 30 minutes followed by transfer to a secondary neutralizing medium, incubation for 48±2 hours at 32.5±2.5°C, and then examination for turbidity / visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The reported average colony forming units per carrier, for each test microorganism, are as follows:

Aspergillus niger **1.1 x 10^4**
Staphylococcus aureus **- Methicillin Resistant** **1.05 x 10^5**

Note: Kirby-Bauer sensitivity was conducted on ***Staphylococcus aureus*** **– MRSA** (ATCC 33591). The zone diameter for the test was 5mm. A zone diameter of <17 mm is considered resistant. A final report including media used, lot numbers, and incubation conditions will be forwarded to the Agency at a later date.

V. RESULTS

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested		Carrier Counts (CFU/ Carrier)
		Lot set ST3-44-1 / ST3-44-3	Lot set ST3-44-2 / ST3-44-4	
471145-01	*Staphylococcus aureus* - Methicillin Resistant	1° 0/10 2° 0/10	1° 0/10 2° 0/10	1.05×10^5
	Aspergillus niger	1° 0/10 2° 0/10	1° 0/10 2° 0/10	1.1×10^4

VI. CONCLUSIONS

1. The submitted efficacy data (MRID No. 471145-01) **support** the use of the product, Sterilex Ultra Disinfectant Cleaner Solution 1(1.0 ml) combined with Sterilex Ultra Cleaner Solution 2 (1.0 ml) and diluted in 10.0 ml of 400 ppm hard water, as a disinfectant with bactericidal activity against *Staphylococcus aureus* - Methicillin Resistant on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 10 minutes at 20°C.

2. The submitted efficacy data (MRID No. 471145-01) **support** the use of the product Sterilex Ultra Disinfectant Cleaner Solution 1 (1.0 ml) combined with Sterilex Ultra Cleaner Solution 2 (1.0 ml) and diluted in 10.0 ml of 400 ppm hard water, as a fungicide against *Aspergillus niger*, when used on hard, non-porous surfaces for a contact time of 10 minutes in the presence of 5% organic soil load at room temperature (20°C).

VII. RECOMMENDATIONS

1. The proposed label claims that the product, Sterilex Ultra Disinfectant Cleaner Solution 1(one part) combined with Sterilex Ultra Cleaner Solution 2 (one part) and diluted in 10 parts of water, is an effective disinfectant against *Staphylococcus aureus* - Methicillin Resistant when used for a contact time of 10 minutes, in the presence of 5% organic soil load, and at room temperature (20°C); **are supported** by the applicant's data.

2. The proposed label claims that the product, Sterilex Ultra Disinfectant Cleaner Solution 1(one part) combined with Sterilex Ultra Cleaner Solution 2 (one part) and diluted in 10 parts water, is an effective fungistat/mildewstat against *Aspergillus niger* (Mold and Mildew), when used for a contact time of 10 minutes, in the presence of 5% organic soil load, and at room temperature (20°C); **are supported** by the applicant's data.

3. The proposed label claims that the product, Sterilex Ultra Disinfectant Cleaner Solution 1(one part) combined with Sterilex Ultra Cleaner Solution 2 (one part) and diluted in 10 parts of water, removes biofilm from dental unit lines, **are acceptable**.

Please note: The species name of these organisms (*Salmonella choleraesius*) has been changed by ATCC. The new designation of this organism is *Salmonella* ***enterica***. This change is effective immediately, and should be used for all subsequent references to this organism in the future.